

Device Analysis Report

Device ID: 99836 Generated: 2025-09-02 10:02:53 Source: Snowflake

Prediction Health

High Risk

Risk %: 75.33
Within 50 days: Yes

Manufacturer

No manufacturer data available

Device Information

CLASSIFICATION : Radiology Devices

CODE : IYE

COUNTRY : USA

DESCRIPTION : Head Ring Posts with part number 970.280 - re-usable components of the Frame Array Module (of the Optical Guidance Platform and Floorstand devices. || Varian Medical Systems, Palo Alto, CA 94304. || The Optical Guidance Platform is for use with a charged particle accelerator to perform precise positioning of treatment for stereotactic radiosurgery or radiotherapy treatments on cranial extracranial lesions.

DISTRIBUTED_TO : Worldwide Distribution.

ID : 99836

IMPLANTED : NO

MANUFACTURER_ID : 16090

NAME : Head Ring Posts; of the Optical Guidance Platform and Floorstand devices

NUMBER : Model H48: Head ring Post part number 970.280 Code numbers: HZ50004 HZ70169 HZ70426 HZ70617 HZ70743 HZ72001 HZ72037 HZ72064 HZ72089 HZ73039 HZ77007 HZ50468 HZ70181 HZ70460 HZ70620 HZ70762 HZ72002 HZ72038 HZ72067 HZ72090 HZ73041 HZ77010 HZ50567 HZ70182 HZ70465 HZ70629 HZ71001 HZ72003 HZ72039 HZ72068 HZ72091 HZ73042 HZ77011 HZ50671 HZ70190 HZ70466 HZ70640 HZ71002 HZ72004 HZ72040 HZ72069 HZ72094 HZ73044 HZ77027 HZ59006 HZ70223 HZ70486 HZ70646 HZ71003 HZ72005 HZ72041 HZ72070 HZ72095 HZ73046 HZ77040 HZ59011 HZ70231 HZ70495 HZ70649 HZ71004 HZ72006 HZ72042 HZ72071 HZ72096 HZ73047 HZ77062 HZ59014 HZ70258 HZ70500 HZ70656 HZ71005 HZ72007 HZ72043 HZ72072 HZ72098 HZ73049 HZ77069 HZ59016 HZ70273 HZ70507 HZ70670 HZ71006 HZ72008 HZ72046 HZ72073 HZ72101 HZ73050 HZ77077 HZ59017 HZ70274 HZ70508

HZ70674 HZ71007 HZ72009 HZ72047 HZ72074 HZ72103 HZ73053 HZ77081 HZ59018 HZ70283
HZ70509 HZ70675 HZ71008 HZ72012 HZ72048 HZ72075 HZ72107 HZ73055 HZ78330 HZ59020
HZ70293 HZ70513 HZ70681 HZ71009 HZ72013 HZ72049 HZ72077 HZ72108 HZ73059
HZ79012 HZ59139 HZ70294 HZ70537 HZ70684 HZ71011 HZ72015 HZ72052 HZ72080 HZ72125
HZ73060 HZ79020 HZ59997 HZ70299 HZ70540 HZ70696 HZ71013 HZ72016 HZ72054 HZ72081
HZ72126 HZ73062 HZ79113 HZ59998 HZ70351 HZ70548 HZ70698 HZ71014 HZ72023 HZ72055
HZ72082 HZ72190 HZ73064 HZ79144 HZ70044 HZ70355 HZ70550 HZ70703 HZ71017 HZ72026
HZ72056 HZ72083 HZ73020 HZ75070 HZ79185 HZ70050 HZ70368 HZ70557 HZ70712 HZ71019
HZ72027 HZ72057 HZ72084 HZ73021 HZ75480 HZ79998 HZ70061 HZ70398 HZ70585 HZ70725
HZ71021 HZ72029 HZ72058 HZ72085 HZ73022 HZ76066 HZ70083 HZ70403 HZ70594 HZ70731
HZ71022 HZ72030 HZ72060 HZ72086 HZ73026 HZ76118 HZ70108 HZ70404 HZ70603 HZ70737
HZ71023 HZ72033 HZ72061 HZ72087 HZ73030 HZ77002 HZ70154 HZ70405 HZ70612 HZ70740
HZ71024 HZ72036 HZ72062 HZ72088 HZ73031 HZ77003.

QUANTITY_IN_COMMERCE : 205 kits (Each kit contains 4 Head Post Rings) 820 HPR's

RISK_CLASS : 2

SLUG : usa-radiology-devices-head-ring-posts-of-the-optical-guidance-platform-and-floorstand-devices

Related Events

Event 1

ACTION : Recall

ACTION_CLASSIFICATION : Class III

ACTION_SUMMARY : Advisory notice to hospitals regarding maintenance and inspection.

DATE_INITIATED_BY_FIRM : 10-09-2018

DATE_POSTED : 08-10-2018

DATE_TERMINATED : 07-11-2018

DATE_UPDATED : 17-10-2018

DEVICE_ID : 99836

ID : 48375

MANUFACTURER_ID : 20887

REASON : Issue detected: battery defect; users instructed to stop use.

STATUS : Ongoing

TYPE : Recall